May 24, 2004

Sarah Loftus McLallen
ACC Petroleum Additives Panel
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. McLallen:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Phosphoric acid, mono (2-ethylhexyl) ester, compound with tert-dodecanamine posted on the ChemRTK HPV Challenge Program Web site on January 23, 2004. I commend the Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG) for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

EPA agrees with the submitter's plan to address the HPV endpoints by testing or utilizing available data through the submission of other (non-submitter) HPV Challenge Program test plans, or a combination of both. The submitter should be aware that any testing conducted under the HPV Challenge Program should be completed by the end of 2004 and robust summaries of the test data should be submitted by the end of 2005. EPA requests that if analog data are utilized a revised test plan be submitted for review. Although not stated in the submission, it is assumed that testing performed will follow appropriate OECD guidelines (for more specific guidance see http://www.epa.gov/chemrtk/ts42213.pdf):

Physicochemical Properties. Melting point (OECD TG 102), boiling point (OECD TG 103), vapor pressure (OECD TG 104), water solubility (OECD TG 105), and octanol:water partition coefficient (OECD TG 107, 117).

Environmental Fate. Photodegradation (estimated usually via EPIWIN/AOPWIN), hydrolysis (OECD TG 111), biodegradation (OECD TG 301), and fugacity (estimated, Level III model preferred).

Health Effects. Acute toxicity (OECD TG 425), repeated-dose/reproductive/developmental toxicity screen (OECD TG 422), gene mutation (OECD TG 471), and chromosomal aberration (OECD TG 473).

Ecological Effects. Acute toxicity to fish, invertebrates, and algae (OECD TG 203, 202, and 201, respectively. Note that measured (actual) concentrations used (as opposed to nominal) should be reported in the robust summaries.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that HERTG advise the Agency of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance

Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber